

SECTION 1-A1 PROTOCOL APPENDIX 1

BASELINE AND FOLLOW-UP VARIABLES

1-A1.1 Variables

Eligibility Screen (Form 2 or 3)-- name; mailing address; telephone numbers and best times to call; date of birth; residing in area for next three years; current involvement in other research studies; history of cancer (site, diagnosis in past 10 years); ethnicity; recruitment source; hormone use (present, in last three months); osteoporosis-related fracture and hormone use as treatment; hysterectomy history; last menstrual bleeding; number of meals prepared away from home; special diets (type); history of diabetes, deep vein thrombosis, pulmonary embolus, stroke, transient ischemic attack, myocardial infarction; history of sickle cell anemia, heart failure, liver disease, bleeding problem; loss of 15 pounds in last six months; renal failure requiring hemodialysis; other chronic illness; emotional or mental problems; ability to get to clinical center; interest in DM; interest in HRT (willingness to stop current hormone medications).

HRT Washout (Form 4)-- date stopped hormones; assessment of symptoms after stopping (HRT for those on hormones at Initial Contact).

Final Eligibility Assessment (Form 6)-- confirmation of eligibility due to medical conditions, depression, substance abuse, staff assessment.

Initial, HRT, DM, CaD, OS, Consents (Form 11 - Consent Status)-- date signed or refused; reasons refused; genetic studies consented or refused.

Personal Information (Form 20)-- name; address; address and telephone number contacts not living with participant; social security number; education; employment status; occupation; marital status; partner's name, social security number, education, employment status, occupation; total family income; primary health care provider's name, address, phone number; recent history of mammogram, pelvic exam, endometrial aspiration; insurance coverage.

Personal Information Update (Form 21)-- name, address, and phone numbers, best time to call; names, addresses, and phone numbers of contacts not living with participant; primary health care provider's name and address.

Medical History (Form 30)-- hospitalization history; history of medical conditions; history of heart, circulatory, or coagulation problems; history of arthritis, gallbladder disease, thyroid disease, hypertension, angina, peripheral arterial disease and related procedures, colonoscopy or sigmoidoscopy, stool guaiac; history of cancers (site, age at diagnosis); recent history of falls or syncopal episodes; history of fractures (site, age, number).

Medical History Update (Form 33)-- hospitalization since last contact; hospitalization for heart, circulatory, or coagulation problems; stroke or transient ischemic attack, number of falls or syncopal episodes, fractures update; cancer (type, where diagnosed, hospitalization); mammogram; breast biopsy, needle aspiration, or lumpectomy; tests and procedures; electrocardiogram; diagnosis of new conditions; hip or other joint replacement.

Reproductive History (Form 31)-- age at menarche; history of menstrual irregularity and amenorrhea; history of menopausal symptoms; history of pregnancy, pregnancy outcomes, infertility; history of breast feeding; history of gynecologic and breast surgeries.

Family History (Form 32)-- number of full-blooded sisters and brothers, daughters, and sons; parental age or date of death; relatives' history of diabetes, myocardial infarction, stroke, cancers; fractures in parents (site, age).

Personal Habits (Form 34)-- coffee consumption; smoking history; alcohol history; weight change; special diets; history of physical activity and exercise (frequency, duration).

Personal Habits Update (Form 35)--physical activity and exercise; alcohol consumption; current cigarette smoking.

Thoughts and Feelings/Daily Life (Form 37)-- social support; social integration; care giving; social strain; optimism; negative emotional expressiveness; hostility; quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.

Daily Life (Form 38)-- quality of life; symptoms; life events; depression; sleep disturbance; urinary incontinence; sexual functioning.

Cognitive Status (Form 39)-- expanded mini mental status examination.

Addendum to Medical History Update (Form 40) -- family history of DVT and PE.

Addendum to Personal Information (Form 41)-- racial/ethnic background using 2000 Census questions.

Hormone Use (Form 43)-- current and past hormone replacement; history of oral contraceptive, diethylstilbestrol, depo-provera use.

Current Medications (Form 44)-- current medication inventory.

Current Supplements (Form 45)-- current dietary supplements inventory.

Estrogen Plus Progestin Survey (Form 49)-- a list of symptom questions.

FFQ (Form 60)-- (145 item Food Frequency Questionnaire)

Four-Day Food Record (Form 62)

24-hour Dietary Recall

Physical Measurements (Form 80)-- blood pressure; resting pulse; height, weight, waist and hip circumference.

Functional status (Form 90)-- grip strength; chair stand; time to walk 6 meters.

Pelvic Exam (Form 81)

Pap Smear (Form 92)

Endometrial Aspiration (Form 82)

Clinical Breast Exam (Form 84)

Mammogram (Form 85)

ECG (Form 86)-- Resting 12-lead electrocardiogram.

Blood collection (Form 100)-- Hemoglobin, hematocrit, white blood cell count, platelet count, fasting triglycerides (as needed for eligibility at baseline); fasting serum, plasma (citrate and EDTA), buffy coat, RBCs for storage.

Medication Dispensation

Medication Adherence

HRT Safety Interview (Form 10)-- presence and amount of vaginal bleeding; changes in breasts; presence of other symptoms or worries, health changes that might require stopping study pills, pill-taking behaviors.

CaD Safety Interview (Form 17)-- presence of gastrointestinal symptoms or other symptoms or concerns, health changes that might require stopping study pills, pill-taking behaviors.

HRT Calendar (Form 53)-- days and amount of vaginal bleeding (HRT women with uterus).

Observational Study Questionnaire (Form 42)-- birth weight, birth status, breast feeding at birth; coffee/tea consumption; alcohol history; smoking history; history of breast examination, history of benign breast disease, recent history of mammogram; history of the use of powders in genital area or on sanitary napkins; history of diaphragm; history electric blanket use; religious affiliation; recent history of physical activity and exercise (frequency, duration); occupational history; height and weight history, weight change; state of residence history.

Observational Study Exposure Update Questionnaires (Example: Form 48)-- annual updates of key exposure information and assessment of selected new exposures.

Observational Study Follow-up Questionnaire Year 1 (Form 48)-- current weight, recent weight change; current food and beverage consumption at meal or snack times, recent use of fats or oils, recent wine consumption; current smoking habits; recent history of hormone replacement; history of insecticide exposure; history of living with pets; history of computer use (frequency, duration); history of hand-held hair dryer use (frequency, duration).

Observational Study Follow-Up Questionnaire Year 3 (Form 143)-- recent weight change, figure (weight) identification; current physical activity and exercise (frequency, duration); past strenuous physical activity (frequency); recent use of fats or oils; recent alcohol consumption, change in alcohol consumption habits; recent coffee/tea/water/diet drinks consumption; current smoking, current smoking exposure; current employment status, current marital status, partner's current employment status ; total family income; existence and recent use of usual medical care provider, change in usual medical provider; choice options in current health insurance coverage, type(s) of current health insurance coverage and payment mechanism; recent use of hormone replacement therapy; diagnoses of new medical conditions.

Observational Study Follow-Up Questionnaire Year 4 (Form 144)-- current weight, recent weight change; current physical activity and exercise (frequency, duration); exposure and sensitivity to sunlight; current smoking; past and present use of artificial sweeteners; recent use of hormone replacement therapy; diagnoses of new medical conditions; current marital status.

Observational Study Follow-Up Questionnaire Year 5 (Form 145)-- current weight, recent weight change, current physical activity and exercise (frequency, duration); current smoking; video; video display terminal exposure; recent emotions; frequency religious practices; recent use of alternative medical treatments; current dental health, frequency of professional dental care; recent use of hormone replacement therapy; diagnoses of new medical conditions; current marital status.

Observational Study Follow-Up Questionnaire Year 6 (Form 146)-- current weight, recent weight change, current physical activity and exercise (frequency, duration); current activities; coffee, tea, soft drink, alcohol consumption; current smoking; smoking exposure; existence and recent use of medical care provider, status

and types of health insurance; use of natural hormones; use of osteoporosis prescription medications; recent use of hormone replacement therapy; diagnoses of new medical conditions; current employment status; current marital status; family finances.

Observational Study Follow-Up Questionnaire Year 7 (Form 147)-- current weight; recent weight change; current physical activity and exercise (frequency, duration); use of weight loss medications; recent use of hormone replacement therapy; diagnoses of new medical conditions; life events; parents birthplace; current marital status.

Observational Study Follow-Up Questionnaire Year 8 (Form 148)-- current weight; recent weight change; current physical activity and exercise (frequency, duration); current smoking status; use of weight loss medications; coffee, tea, soft drink consumption ; recent use SERMS, recent use of hormone replacement therapy; diagnoses of new medical conditions; family history of senile dementia.

Bone Density Scan (Form 87)-- (osteoporosis substudy sites only)

Urine collection (Form 101)-- Urine for storage (osteoporosis substudy sites only).

1-A1.2 Frequency of Collection

See *Table 1-A1.1* for frequency of data collection.

Table 1-A1.1
Frequency of Data Collection

	Screening ¹ CT and OS				CT																					OS			
	SV 0	SV 1	SV 2	SV 3	4-6 wk s	6 m	1 Yr	4 wk	6 m	2 Yr	6 m	3 Yr	6 m	4 Yr	6 m	5 Yr	6 m	6 Yr	6 m	7 Yr	6 M	8 Yr	6 m	9 Yr	Close Out	Annual	3 Yr	6 Yr	9 Yr
Eligibility Screen	X			*																									
HRT Washout		X																											
Final Eligibility Assessment		X																											
Initial Consent		X																											
HRT Consent			X																										
DM Consent			X																										
CaD Consent							X																						
Personal Information		X																											
Personal Information Update			*	*	*	*	*		*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		*	*	*
Medical History		X																											
Medical History Update						X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
Reproductive History			X																										
Family History				X																									
Personal Habits				X																									
Personal Habits Update							X					X					X							X					
Thoughts & Feelings/Daily Life			X																						X				
Daily Life							X					%					%							%			X		
Cognitive Status				%H			%H					%H					%H						%H						
Hormone Use		X																											
Current Medications		X		*			X					X					X							X			X		
Current Supplements		X		*			X					X					X							X			X		
Personal Habits Update							X					X					X							X					
FFQ		X					D			%D		%D		%D		%D		%D		%D		%D		%D			X		
Four-Day Food Record				D			%D																						
24 Hour Dietary Recall				%D			%D			%D		%D		%D		%D		%D		%D		%D		%D					
Physical Measures		X					X			X		X		X		X		X		X		X		X			X	BD	
Waist/Hip Measures		X					X					%					%							%					
Functional Status				%			%					%					%							%					
Pelvic (in women with uterus) ^{2,3}			H				H			H		H		H		H		H		H		H		H					
Pap (in women with cervix) ^{2,3}			H									H					H							H					
Endometrial Evaluation																													
(in women with uteri) ³			H									%H					%H							%H					

	Screening ¹ CT and OS				CT																				OS				
	SV 0	SV 1	SV 2	SV 3	4-6 wk s	6 m	1 Yr	4 wk	6 m	2 Yr	6 m	3 Yr	6 m	4 Yr	6 m	5 Yr	6 m	6 Yr	6 m	7 Yr	6 M	8 Yr	6 m	9 Yr	Close Out	Annual	3 Yr	6 Yr	9 Yr
Clinical Breast Exam			HD				H			H		H		H		H		H		H		H		H					
Mammogram			HD				H			X		H		X		H		X		H		X		H	X				
ECG			HD									X						X						X					
Blood Collection		X					X					%						%						%			X		
Medication Dispensation ^{3,4}			H	H		H	HC			HC		HC		HC		HC		HC		HC		HC		HC					
Medication Adherence				H		H	H		HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	C			
Safety Interview ⁵					H	H	H	C	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	HC	C				
HRT Calendar				H		H																							
OS Consent		X																											
OS Questionnaire		X																											
OS Exposure Update ⁶																										X			
Bone Densitometry		BD					BD					BD						BD						BD			BD	BD	BD
Urine Collection		BD					BD					BD												BD			BD		BD

Key

X = All Participants

D = DM

H = HRT

HC = HRT and CaD

% = Percentage (subsample) of participants

BD = Bone Density sites

* = "Update"

Notes¹ According to screening model, all screening tasks must be completed by SV3.² Pelvic and Pap performed in all HRT women during screening.³ These tasks are not required for Estrogen plus Progestin (PERT) participants since study pills were stopped on July 9, 2002.⁴ Clinic option to dispense a six-month supply of study pills semi-annually.⁵ Safety interviews are only required while HRT or CaD participants are taking study pills and for two semi-annual contacts (HRT) or one semi-annual contacts (CaD) after stopping.⁶ OS Exposure Update not done at year 2.

Section 1-A1
Protocol Appendix 1
Baseline and Follow-Up Variables

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